

Application No. 10/524,104
Amendment dated July 17, 2007
Reply to Office Action of May 17, 2007

Docket No.: 3535-013&PUSI

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REMARKS

Applicant appreciates the Examiner's consideration provided in the present application. Claims 1-5 and 9-14 are now present in the application. Reconsideration of this application, as amended, is respectfully requested.

Claim Rejection Under 35 U.S.C. §101

Claims 6-8 are alleged to be non-statutory under 35 U.S.C. §101. This rejection is respectfully traversed.

Claims 6-8 have been canceled. Examiner's rejection under 35 U.S.C. § 101 has been rendered moot with regard to these claims.

Claim Objection

The Examiner requests to amend claims 2 and 7 to correct some misspellings. This request is respectfully traversed.

The misspelling in claim 2 has been corrected, and claim 7 has been canceled. Accordingly, Applicant respectfully requests that the objection to the claims be withdrawn.

Election/Restrictions

The Examiner has required Applicant to elect a single invention among Groups I, II and III because the uniting feature of the present application does not contribute over the prior art, Breton et al. (US Patent No. 5,851,556). For the purpose of examination of the present application, Applicant elects Group I, claims 1-5, and respectfully traverses the Examiner's election of species requirement for the following reasons.

Application No. 10/524,104
Amendment dated July 17, 2007
Reply to Office Action of May 17, 2007

Docket No.: 3535-0138PUS1

First, as appears in the title and abstract of Breton et al., the Breton reference primarily relates to the use of a salt of alkaline-earth metal in a cosmetic, pharmaceutical, veterinary and/or dermatological composition for treating, in particular, sensitive skins and for preventing or combating skin conditions such as rosacea, skin irritation, darter, pudic erythema, dysesthetic sensation, sensation of inflammation, pruritus of the skin and of the mucous membranes. Additionally, the document teaches that compositions of this invention can include a neuropeptide or inflammatory mediator antagonist.

Second, Breton et al. discuss in Column 2, lines 54-65 that in a test to determine whether a skin is sensitive or not, capsaicin (a known irritant, the active component of chili peppers) was applied to skin. Capsaicin causes a release of neuropeptides from the sensitive nerve fibers, such as substance P and CGRP peptide from nerve endings of the epidermis and the dermis. Breton et al. observed that sensitive skins appeared to be linked to a high capacity to release neuropeptides.

In Column 3, lines 5-16, Breton et al. discuss the biological role of the neuropeptides substance P and CGRP and state that CGRP is involved in respiratory and inflammatory diseases, allergic and rheumatic diseases, and in some dermatological diseases such as eczema, urticaria, contact dermatitis or prurigo. Notably, an association of CGRP with psoriasis is however not suggested or disclosed. In this context, it must be noted that apart from being a skin disease, psoriasis is a biologically different disease than the above mentioned.

Breton et al. postulate (in Column 3, lines 20-24) that "molecules which prevented the release of these neuropeptides [substance P and CGRP] and/or the release of TNF-a could make it possible to obtain a preventive and/or curative effect for sensitive skins."

Further down in Column 3, lines 60-65, the pruritus symptom is discussed generally. It is stated that pruritus is "not only associated with sensitive skin, but also with skin disorders such as atopic dermatitis, contact dermatitis, lichen planus, prurigo, urticaria, pruriginous toxiderma and some clinical forms of psoriasis (emphasis added)."

Application No. 10/524,104
Amendment dated July 17, 2007
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Docket No.: 3535-0138PUS1

From the above it is in fact quite clear that Breton et al. do not teach or suggest a CGRP antagonist for treating, remedying or preventing psoriasis, as they clearly distinguish psoriasis from sensitive skin conditions, with which they associate release of neuropeptides. Furthermore, It should be emphasized that Breton et al. only disclose cosmetic/phrmaceutical compositions which are combinations of an alkaline-earth metal and an antagonist, in which the former component is indicated as the main component, from the disclosure as a whole.

In other sections of the disclosure where neuropeptide antagonists are mentioned (Column 8, lines 1-11 and Column 8 line 56 to Column 9, line 13), no mention is made of psoriasis.

Psoriasis is mentioned in Column 9, lines 48-63, where a list of multiple forms and formulations (creams, lotions etc.) of the compositions of the disclosure (i.e., with alkaline earth metal salt and antagonist) is presented for all sorts of cosmetic purposes as well as several unrelated skin conditions - severe pruritus, rosacea, acne, ulcers of the leg, psoriasis, pustules, and vibex. No reasoning is provided as to why psoriasis is listed and whether and how psoriasis is linked to these other diseases (i.e., a link other than the obvious that these are diseases of the complex organ which is the skin).

Finally, psoriasis is mentioned in claim 28, which claim relates to a method for treating a condition selected from a group including psoriasis, the method comprising administering a strontium salt.

To summarize, neither the claims nor the description of Breton et al. teach CGRP antagonists for the treatment of psoriasis or demonstrate in any way why CGRP antagonists should be used for this purpose.

In view of the above remarks, Applicant respectfully submits that the Examiner's election of species requirement is improper and should be withdrawn. If the Examiner persists in this

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CENTRAL FAX CENTER Docket No.: 3535-0138PUS1
JUL 17 2007

election of species requirement, Applicant reserves the right to petition the Examiner under 37 C.F.R. § 1.144.

Species Election

First, the Examiner submits that if any one of Groups I-III is elected, Applicant is required to elect one species of CGRP antagonist compound recited in claim 2.

For the purpose of examination of the present application, Applicant elects, with traverse, CGRP derivatives including the peptide CGRP 8-37.

Second, the Examiner submits that if Group I is elected, Applicant is required to elect one species of administering routes recited in claims 3-5.

For the purpose of examination of the present application, Applicant elects claim 5 with traverse. Applicant has not canceled the non-elected claims 3 and 4 since each of these claims depends, either directly or indirectly, from independent generic claim 1, which is believed to be allowable. Upon allowance of independent claim 1, Applicant respectfully requests examination and allowance of these withdrawn claims.

Conclusion

Favorable reconsideration and an early Notice of Allowance are earnestly solicited. Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Joe McKinney Muncy, Reg. No. 32,334, at the telephone number below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

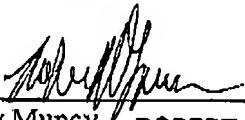
Application No. 10/524,104
Amendment dated July 17, 2007
Reply to Office Action of May 17, 2007

Docket No.: 3535-0138PUS1

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: July 17, 2007

Respectfully submitted,

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